



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 3 2005

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Marvin J. Garrett
Vice President, Regulatory Affairs and
Quality Assurance & Compliance
ISTA Pharmaceuticals, Inc.
15295 Alton Parkway
Irvine, CA 92618

Re: Docket No. 2005P-0134/CP1

Dear Mr. Garrett:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on April 6, 2005. Your petition requests that FDA reverse its decision to grant ISTA a 5-year period of marketing exclusivity for its naturally sourced hyaluronidase product, Vitrase (NDA 21-640). You request that FDA instead grant ISTA a 3-year period of marketing exclusivity for this product.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2005P- 0134

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